DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-377/S-013

Wyeth Pharmaceuticals, Inc.
Attention: Ms. Patricia Kuker Staub
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Ms. Kuker Staub:

Please refer to your supplemental new drug application dated April 8, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cordarone (amiodarone HCl) Intravenous 50 mg/ml.

This "Changes Being Effected" supplemental new drug application provides for final printed labeling revised to read as follows:

Under **PRECAUTIONS/Pediatric Use**, the following has been added to the first paragraph:

> In a pediatric trial of 61 patients, aged 30 days to 15 years, hypotension (36%), bradycardia (20%), and atrio-ventricular block (15%) were common dose-related adverse events and were severe or life-threatening in some cases. Injection site reactions were seen in 5 (25%) of the 20 patients receiving Cordarone I.V. through a peripheral vein irrespective of dose regimen.

We have completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on April 8, 2003.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Mr. Russell Fortney
Regulatory Health Project Manager
301-594-5311

Sincerely,

{See appended electronic signature page}

Douglas C. Throckmorton, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Doug Throckmorton
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